K070816
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## Section 5: 510(k) Summary

SEP 19 2007

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| **Submitter's Information** | Micrus Design Technology<br>9344 NW 13 Street<br>Miami, Florida 33172 USA<br>Telephone: 1-305-477-2406<br>Contact: Marianne Grunwaldt, MS, CQE |
| **Preparation Date** | 19 March 2007 |
| **Name of Device** | Common/Classification Name: Catheter Introducer<br>Trade Name: Micrus Design Technology Peripheral Guiding Sheath |
| **Predicate Devices** | Terumo Pinnacle Destination<br>Cook Shuttle/Flexor |
| **Intended Use** | Micrus Design Technology Peripheral Guiding Sheaths are intended for use in arterial and venous procedures requiring percutaneous introduction of intravascular devices. |
| **Device Description and Summary of Technological Characteristics** | The Micrus Design Technology Peripheral Guiding Sheaths are single lumen catheters, incorporating a Pebax® body reinforced with a stainless steel wire coil. The intermediate segment is also Pebax® with a stainless steel coil to reduce kinking and to promote improved torque response. They are available in 5 Fr, 6Fr, 7Fr, and 8 Fr and 45 cm, 55 cm and 90 cm in length, and in a variety of shapes. The technological characteristics are equivalent to the predicate device. |
| **Testing Summary** | Mechanical laboratory testing has been performed on the Micrus Design Technology Peripheral Guiding Sheaths to assure compliance to the specifications. In addition, testing has been performed on the materials to assure biocompatibility. |
| **Conclusions** | The non-clinical tests as discussed above demonstrate that, like the predicate devices, the Micrus Design Technology Peripheral Guiding Sheath is safe and effective for its intended use. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 19 2007

Micrus Design Technology, Inc.
c/o Ms. Marianne Grunwaldt, MS, CQE
Product Assurance Engineer
9344 NW 13 Street
Miami, FL 33172

Re: K070816
Trade/Device Name: Peripheral Guiding Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: July 25, 2007
Received: July 27, 2007

Dear Ms. Grunwaldt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vachner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K070816

Device Name: Micrus Design Technology Peripheral Guiding Sheath

Indications for Use:

Micrus Design Technology Peripheral Guiding Sheaths are indicated for arterial and venous procedures requiring percutaneous introduction of intravascular devices.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K070816